

COMMITTEES:

APPROPRIATIONS

COMMERCE, SCIENCE, AND
TRANSPORTATION

ENVIRONMENT AND
PUBLIC WORKS

United States Senate

WASHINGTON, DC 20510

January 26, 2010

The Honorable Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

I commend the Food and Drug Administration's (FDA's) ongoing efforts to evaluate and regulate electronic cigarettes. Unfortunately, the D.C. District Court's recent opinion in *Smoking Everywhere v. FDA* is a setback to the FDA's efforts to prevent harmful electronic cigarettes from entering the country. I urge you to appeal the preliminary injunction in the *Smoking Everywhere* case and persevere in your efforts to regulate electronic cigarettes as drug-device combinations.

As you know, companies market electronic cigarettes as alternatives to traditional cigarettes and other tobacco products. When the smoker inhales through the battery-powered device, air flow is detected by a sensor, which activates a heating element that vaporizes a nicotine solution stored in the mouthpiece. This vapor may also be flavored and provide a physical sensation similar to that of inhaling tobacco smoke.

Numerous manufacturers of electronic cigarettes claim their products are safe alternatives to smoking tobacco. However, there have been no clinical studies to verify the safety of these products or the long-term health effects. To the contrary, FDA's own laboratory analyses of electronic cigarette samples found them to contain carcinogens and toxins such as antifreeze components. In addition, public health experts have indicated that electronic cigarettes potentially increase nicotine addiction and tobacco use in young people.

Last March, I requested that the FDA take immediate enforcement action against manufacturers of electronic cigarettes and take the products off the U.S. market. I appreciated the FDA's response, which indicated that electronic cigarettes found to qualify as drugs or devices under the Food, Drug, and Cosmetic Act were being refused admission to the United States because they lacked the required FDA approval. I also awaited further steps by the FDA to address concerns about these products.

Unfortunately, the FDA's authority to regulate and refuse admission to electronic cigarettes has been questioned in the recent decision in the *Smoking Everywhere* case. The court found that FDA lacks the authority to regulate electronic cigarettes as drug-

device combinations, and that it must instead treat electronic cigarettes as tobacco products under the Family Smoking Prevention and Tobacco Control Act. I disagree with the decision in this case and support the FDA's position that electronic cigarettes are drug-device combinations. Accordingly, I urge the agency to appeal the ruling and continue to defend its authority to prevent electronic cigarettes from being sold in the marketplace unless their safety and efficacy have been proven, as well as to address the misleading product claims made by manufacturers.

Thank you for your consideration of this request and your continued commitment to protecting the nation's health and safety.

Sincerely,

A handwritten signature in blue ink that reads "Frank R. Lautenberg". The signature is written in a cursive, flowing style with a large initial "F" and a prominent "L".

Frank R. Condit